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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,911	09/05/2003	Arturo J. Angel	524522000500	7674

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/655,911		ANGEL ET AL.	
	Examiner		Art Unit	
	Lakshmi S. Channavajjala		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Upon reconsideration, examiner has withdrawn the finality of the last office action. However, after a careful review of all the pending claims, the following restriction requirement has been made. Since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, examiner has withdrawn the finality of the last office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, drawn to a composition and a kit, classified in class 424, subclass 401.
- II. Claims 23 and 25-33, drawn to a method of treatment, classified in class 424, subclasses 449 and 401.
- III. Claims 24 and 34-44, drawn to a method of cleansing, classified in class 424, subclass 406 or class 510, various subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of group I

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can be used not just providing treatment to pain, hyperalgesia or inflammation etc., but also for cleansing body surfaces, without actually providing any treatment.

Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of group I can be used not just for cleansing body surfaces, but also for providing treatment to conditions such as pain, hyperalgesia or inflammation etc., which method is different from cleaning bodily surfaces.

Inventions III and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the method of cleansing bodily surface is different from a method of treatment pain or other conditions claimed.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. The claimed inventions have been classified in several different classes and subclasses such as 424/449, 424/401, class 510 etc., and a search involving these various classes and subclasses is burdensome.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. A search for the method of treating pain does not encompass a method of cleansing bodily surface with the claimed composition. Further, the composition (and kit) claimed does not require a search for a method of treatment because the composition is not always used for treating a condition. Thus, the claimed inventions require different field of search and therefore burdensome.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

If applicants elect a single group, they are further required to elect a species because this application contains claims directed to the following patentably distinct species:

Group I directed to composition and kit contains the following species:

- I. The composition and a kit, which is a patch.
- II. The composition and a kit, which is not a patch.

Upon electing a single species, applicants are further required to elect single sub-species from the following:

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1. A kit and a composition comprising capsaicin and a second composition comprising a substance in which capsaicin has a solubility of at least 10% w/w.

2. A kit and a composition comprising capsaicin and a second composition comprising a substance in which capsaicin has a solubility of at least 10% w/w, wherein the second composition comprises polyethylene glycol and a polyacrylate thickening agent.

3. A kit and a composition comprising capsaicin and a second composition comprising a substance in which capsaicin has a solubility of at least 10% w/w, further comprising a third composition comprising an anesthetic.

4. A kit and a composition comprising capsaicin and a second composition comprising a substance in which capsaicin has a solubility of at least 10% w/w, wherein the second composition comprises polyethylene glycol and a polyacrylate thickening agent, further comprising a third composition comprising an anesthetic.

Group II directed to a method of treatment contains the following species:

- I. A method, wherein the composition is applied as a patch.
- II. A method, wherein the composition is applied as a lotion or gel.

Upon electing a single species, applicants are further required to elect single sub-species from the following methods:

- 1. Pain
- 2. Inflammatory hyperalgesia

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3. Dermatitis,
4. Pruritis,
5. Itch
6. Psoriasis
7. Warts
8. Headaches
9. Wrinkles
10. Skin cancer

The species are independent or distinct because a patch containing the claimed substance is structurally different from a composition that is not in the form of a patch i.e. a lotion or a gel. Further, a composition containing a specific substance i.e., a combination of polyethylene glycol and a thickening agent is distinct from a composition containing any solubilizing substance as a second compound. Similarly, a composition without a second active agent i.e., anesthetic agent is different from a composition with an active agent. Finally, each of the claimed methods of treatment are independent because a treatment for psoriasis does not necessarily include a treatment for headache, which in turn does not necessarily include a treatment for skin cancer. In each of the above species and sub-species, a search for one species or sub-species does not necessarily encompass a search for the other species and sub-species. Accordingly, the requirement for election of species is proper.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 23-25 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 7, 2006